REMARKS

Responsive to the Final Rejection dated March 6, 2003 (hereinafter "Final Rejection"), amendments have been proposed to claims 1, 8, 10, 26 and 29. Claim 1 has been amended to require that the stent and foil sheet be separate devices. Claim 10 has been amended to require that the flexible substrate and stent are separate devices. Claim 26 has been amended to require that the flexible substrate and insertion device are separate devices. Claim 8 has been amended to make a minor clarification to the wording. Claim 29 has been amended to correct a typographical error by replacing the reference to "foil sheet" with "flexible substrate." Entry of these amendments to place the application in condition for allowance, or in better form for appeal, is respectfully requested.

In the Final Rejection, pending claims 1-35 were rejected as being anticipated by U.S. Patent No. 6,261,320 to Tam et al. (hereinafter "Tam").[1] The applicant considers that pending claims 1-26 and 28-35, as amended, are novel and inventive with respect to the Tam patent. Reconsideration is therefore requested for the following reasons.

The present invention, as claimed in claim 1, differs from the device set forth in Tam in that Applicant's invention requires two separate structural elements, namely, a stent and a foil sheet comprising a radioactive material and located adjacent to the stent. Tam describes only a radioactive stent and therefore Tam's device lacks one of the two structural elements of applicant's claimed invention.

In the Final Rejection, the Examiner remarked that,

> "...it is noted that the features upon which applicant relies (i.e., 'two-element structure') are not recited in the rejected claim(s)....The requirement of the *claimed* foil sheet is only that it be 'located adjacent the stent.' The claims do not require for the stent and foil sheet to be unattached or separate, only 'adjacent' to one another."

Final Rejection at page 3. In order to address the Examiner's concern, all of the independent claims 1, 10 and 26 have been amended to expressly require that the devices must be separate. Basis for the amendment can be found in the figures of the present application and their accompanying description, which show and describe several embodiments of the devices as separate devices.

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[1] The rejection of claim 27 appears to be an error since claim 27 was canceled by the amendment filed on 13 January 2003.

Applicant notes that the presently claimed structure provides many advantages over the radioactive stent of Tam. For example, radioactive sheets are more economically manufactured than radioactive stents. Also, the radioactive stents described by Tam must be produced in different sizes to fit the vessel requiring support; applicant's invention, however, can be conveniently trimmed to the necessary size at the time of use and can be used with non-radioactive stents that are already in inventory. These and other advantages of applicant's invention specifically result from the claimed two-element structure.

Claim 10 as amended herein also requires two separate structural elements, a stent and a flexible substrate, and therefore is also believed to be novel over the device described in Tam for the reasons set forth above.

Claim 26 now also requires two separate structural elements, the flexible substrate and an insertion device selected from a stent and an expandable catheter.

To further clarify the novelty of the present invention over the device set forth in Tam, applicant has also amended Claim 26 to specify that the positioning of the flexible substrate at a desired position within the treatment zone is done, relative to the separate insertion device. Thus, claim 26 differs from Tam in that it requires both a flexible substrate and a separate insertion device and because the separate insertion device of claim 26 expands radially to conform the flexible substrate to the treatment zone. In Tam there is no expandable insertion device that is separate from the flexible substrate.

In addition, although Tam discloses that the stent can be inserted by a catheter insertion device, the catheter of Tam does not expand radially to conform a flexible substrate to the treatment zone as is also required by claim 26 of the present application. Thus, both the structure and the steps in amended claim 26 include elements that do not appear in Tam. Accordingly, claim 26 as amended is also believed to be novel over the method described in Tam.

The Examiner relied on the following quotation from Tam in the Final Rejection,

> The term 'coating' is intended to cover generically any form of material which is adhered to or deposited on or adjacent the surface of the stent, such as a jacket or thin film...

See col. 20, lines 19-22 of Tam. This quotation from Tam makes it clear that Tam does not contemplate a separate insertion device and flexible sheet as in the present invention since the coating must be "adhered to or deposited on or adjacent the surface of the stent." The use of the

terms, "adhered to" and "deposited on" make it clear that the coating becomes part of the stent and is not part of a separate device as in the present invention.

A review of other portions of the Tam reference show that the reference in Tam to a coating "deposited adjacent the surface of the stent" is meant to cover the embodiment wherein the stent is first provided with a "tie layer" and then the radioactive coating is deposited on the "tie layer." See e.g. col. 29, lines 14-47 of Tam. The "tie layer" of Tam is provided to improve the adherence of the radioactive material to the stent. Thus, the reference to depositing a coating "adjacent the surface of the stent" in Tam still refers to a device wherein the stent and radioactive coating are formed integrally and not as two separate elements as in the present invention.

The integral nature of the Tam device is confirmed by the fact that Tam does not describe any embodiments where the stent and radioactive material are two separate devices and by the following statement of one of the advantages of the Tam device found at col. 26, lines 63-66 of Tam:

> Another advantage of the present invention is that the radioisotopes are held by strong atomic-level bonding interactions, and which are highly resistant to leaching or release under physiological conditions.

The discussion in Tam of a "tie layer" and the further discussion in Tam at col. 31, line 48 to col. 32, line 51 of the provision of an outer coating layer on the stent to prevent radioactive material from separating from the stent during use, highlights another advantage of the present invention. Specifically, since the radioactive material of the present invention is provided with a separate flexible sheet, the skilled person need not worry about the Tam problem of finding a way to acceptably adhere the radioactive material to the stent material. Rather, in the present invention, the radioactive material is not adhered to the stent material and thus this problem is eliminated. Instead, the skilled person can choose the material used in the flexible sheet, independent of what material is used to make the stent, in order to avoid problems with adherence of the radioactive material.

Also, the reference at col. 20, lines 19-22 of Tam to a "thin film or jacket" is a reference to a thicker coating as is clear from the fact that these embodiments are given as examples of a coating at col. 20, lines 19-22 and from the statement at col. 32, lines 9-13 of Tam which reads as follows:

> In an alternative embodiment, the coating may take the form of a relatively thicker cover such as a film or jacket, such as having a thickness measured in ten thousandths or one thousandths of an inch or greater.

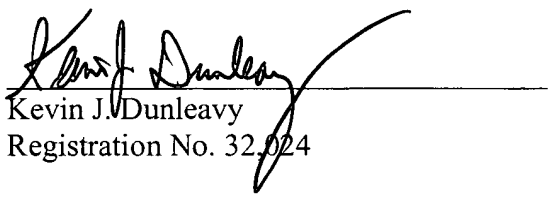
This quotation from Tam confirms that the reference to a "film or jacket" is just a reference to a thicker coating.

Claims 2-9, 11-25, and 28-35 depend from independent claims 1, 10, and 26, respectively. Because the independent claims in the present application are believed to be novel over Tam, it follows that the dependent claims are also novel over Tam for at least the same reasons. Favorable consideration and withdrawal of the rejection of claims 1-26 and 28-35 under 35 U.S.C. §102(e) as anticipated by Tam, is requested.

In conclusion, all claims are considered to be novel in view of Tam for the reasons discussed above. In addition, all claims are considered to be inventive over Tam since Tam does not teach or suggest the features listed above which render the claims novel over Tam, nor is there any motivation to modify the device or method of Tam to arrive at the present invention as claimed in the pending claims. Moreover, all claims are considered inventive on the basis of the several advantages described above, which are provided by the presently claimed device, relative to the device of Tam.

Favorable consideration, entry of the amendments and issuance of a Notice of Allowance are requested.

Respectfully submitted,



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